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EXAMINER	
HOLT, ANDRIAE M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,574	BERNER ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-29* is/are pending in the application.

4a) Of the above claim(s) *15-17 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 18-20, and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed October 15, 2008. Claims 1-20 and 22-29 are pending in the application. Claims 1, 8, and 22 have been amended. Claims 27-29 are newly added. Claims 15-17 were withdrawn from consideration as being drawn to a nonelected species in the previous office action. Newly added claim 29 is withdrawn from consideration as being drawn to a nonelected species. Claims 1-14, 18-20, and 22-28 will presently be examined to the extent they read on the elected subject matter of record.

Status of the Claims

Double Patenting

The examiner notes applicants request to hold the double patenting rejection in abeyance.

The rejection of claims 1, 5, and 11-13 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 21-23 of copending Application No. 10/773,986 (Application '986) **is maintained**.

The rejection of claims 18-20 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52 and 65-66 of copending Application No. 10/281,284 (Application '284) **is maintained.**

Claims 1, 5, and 11-13 of this application conflict with claims 17, 21 and 23 of Application No. 10/773,986. Claims 18-20 of this application conflict with claims 52 and

65-66 of Application No. 10/281,284. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, and 11-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 21-23 of copending Application No. 10/773,986 (Application '986). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed toward a method of delivering a pharmacologically active agent by orally administering to a patient in the fed mode a therapeutically effective amount of the active agent and at least one biocompatible, hydrophilic polymer that swells upon absorption of water from gastric fluid in order to promote gastric retention. In instant claim 1, the dosage form is characterized by an erosion rate to dissolution rate ratio determined by in vitro disintegration tests and in vitro dissolution tests. Claim 17 in Application '986 claims the dosage form gradually erodes within the stomach over a determinable period of time and releases the active ingredient throughout the determined time period and that the dosage form is selected by subjecting the dosage form to a disintegration test in vitro. The instant application does not specifically recite that the dosage form will gradually erode and release the active agent throughout the determinable time period, however, it would be obvious to one skilled in the art, that if the claims possess the same active agent and biocompatible, hydrophilic polymers,

they would erode within the stomach and release the active agent throughout the determinable time period. In reference to instant claims 5, 11 and 13, using the method of delivering a pharmacologically active agent wherein at least 85% of the active agent is released within six to eight hours is identical to claim 21 of Application '986. The active agent of instant claims 11 and 13 is the antibiotic ciprofloxacin, which is the same anti-microbial agent in Application '986. Therefore the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52 and 65-66 of copending Application No. 10/281,284 (Application '284). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed toward a method of treating a mammal by orally administering ciprofloxacin to a mammal in a fed mode once daily. The instant claims specifically state a method of treating a human patient. Application '284 uses the term "mammal". It is known in the art that a human patient is a mammal; therefore it would be obvious to treat a human with the pharmacologically active agent, ciprofloxacin once daily as claimed in Application '284. Therefore the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The rejection of claims 1-10 and 22-26 under 35 U.S.C. 102(b) as being anticipated by Shell et al. (US 5,972,389) **is withdrawn** due to applicant's amendment of the claims.

The rejection of claims 1-3 and 22-24 under 35 U.S.C. 102(b) as being anticipated by Wong et al. (US 6,120,803) **is withdrawn** due to applicant's amendment of the claims.

The rejection of claims 1-3, 11-14 and 18-20 under 35 U.S.C. 103 (a) as being unpatentable over Shell et al. (US 5,972,389) in view of Louie-Helm et al. Publication (2001) and Cipro® Drug Information Sheet (2000) **is withdrawn** due to applicant's amendment of the claims.

New Rejections Necessitated by Amendment filed October 15, 2008

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Shell et al. (US 2001/0018070).

Shell et al. disclose a formulation in which the drug is dispersed in a polymeric matrix that is water-swellable rather than merely hydrophilic and that has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion. Shell et al. further disclose that it has been found that the rate of diffusion of the drug out of the matrix can be slowed by increasing the drug particle size, by the choice of polymer used in the matrix, and/or by the choice of molecular weight of the polymer. Shell et al. disclose the matrix is a relatively high molecular weight polymer that swells upon ingestion, preferably to a size that is at least about twice its unswelled volume, and that promotes gastric retention during the fed mode. Shell et al. disclose the penetrating fluid then causes release of the drug in a gradual and prolonged manner by the process of solution diffusion, i.e., dissolution of the drug in the penetrating fluid and diffusion of the dissolved drug back out of the matrix. Shell et al. disclose the matrix itself is solid prior to administration and, once administered, remains undissolved in (i.e., is not eroded by) the gastric fluid for a period of time sufficient to permit the majority of the drug to be released by the solution diffusion process during the fed mode. The rate-limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix rather than erosion, dissolving or chemical decomposition of the matrix (page 3, paragraph 24).

Shell et al. disclose that for highly soluble drugs, the swelling of the polymeric matrix thus achieves two objectives--(i) the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode, and (ii) it retards the rate of diffusion of the highly soluble drug long enough to provide multi-hour, controlled delivery

of the drug into the stomach (polymer matrix with active, maintains size for an extended period of time). Shell et al. further disclose for drugs that are either sparingly soluble, of limited solubility, or of high solubility, and that experience any of the specific problems enumerated above upon reaching the lower GI tract prior to absorption into the bloodstream, the swelling of the polymeric matrix (i) renders the matrix sufficiently large to cause retention in the stomach during the fed mode, and (ii) localizes the release of the drug to the stomach and small intestine so that the drug will have its full effect without colonic degradation, inactivation, or loss of bioavailability (page 3, paragraph 25). Shell et al. disclose that the invention also provides enhanced absorption of soluble drugs that are absorbed mostly in the stomach or high in the gastrointestinal tract, such as metformin hydrochloride or ciprofloxacin (ciprofloxacin) (page 4, paragraph 26).

Shell et al. disclose the water-swellable polymer forming the matrix is any polymer that is non-toxic, that swells in a dimensionally unrestricted manner upon imbibition of water, and that provides for sustained release of an incorporated drug (swells upon imbibition of water to promote gastric retention)(page 4, paragraph 40). Shell et al. disclose that the release rate of a drug from the matrix is primarily dependent upon the rate of water imbibition and the rate at which the drug dissolves and diffuses from the swollen polymer, which in turn is related to the solubility and dissolution rate of the drug, the drug particle size and the drug concentration in the matrix.

Shell et al. disclose the amount of polymer relative to the drug can vary, depending on the drug release rate desired and on the polymer, its molecular weight, and excipients that may be present in the formulation. Shell et al. disclose the amount

of polymer will be sufficient however to retain at least about 40% of the drug within the matrix one hour after ingestion (or immersion in the gastric fluid). Shell et al. disclose that preferably, the amount of polymer is such that at least 50% of the drug remains in the matrix one hour after ingestion, more preferably, at least 60%, and most preferably at least 80%, of the drug remains in the matrix one hour after ingestion. In all cases, however, the drug will be substantially all released from the matrix within about ten hours, and preferably within about eight hours, after ingestion, and the polymeric matrix will remain substantially intact until all of the drug is released (page 5, paragraph 46) (dosage form in upper GI tract 2 to 12 hours and 4 to 9 hours, at least 75 to 85 wt % of active released). Shell et al. disclose preferred loadings are those within the range of 15% to 80%, more preferably within the range of 30% to 80%, and most preferably in certain cases within the range of about 30% to 70% (therapeutically effective amount is 0.01% to 80%) (page 5, paragraph 48).

Shell et al. disclose the formulations of this invention may assume the form of tablets (page 5, paragraph 49). Shell et al. disclose the drug-impregnated polymer matrix can be prepared by various conventional mixing, comminution and fabrication techniques readily apparent to those skilled in the chemistry of drug formulations (page 6, paragraph 52). Shell et al. disclose in example 2 the controlled release behavior of captopril from a polymeric matrix consisting of poly (ethylene oxide), both with and without glyceryl monostearate (page 8, paragraph 81).

Shell et al. meet all the limitations of the claims and thereby anticipate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 and 22-28 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Shell et al. (US 2001/0018070) in view of Hallmark Pharmaceuticals (WO 96/26717) (Hallmark '717).

Applicant's Invention

Applicant claims a method of delivering a pharmacologically active comprising orally administering to a patient in a fed mode a matrix/active tablet dosage form comprised of a polymer matrix and a pharmacologically active agent dispersed in the polymer matrix. Applicant further claims the dosage range form maintains its size for an

extended period of time before it is diminished by erosion. Applicant claims the dosage form is characterized by an erosion rate to dissolution rate ratio of approximately 1.1:1 to 5:1.

Determination of the scope of the content of the prior art (MPEP 2141.01)

The teachings of Shell et al. are incorporated herein by reference and are therefore applied in the instant rejection as discussed above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Shell et al. do not teach the dosage form is characterized by an erosion rate to dissolution rate ratio of approximately 1.1:1 to 5:1. It is for this reason Hallmark ‘717. ‘389 is joined as a secondary reference.

Hallmark ‘717 teaches verapamil depot drug formulations that include the pharmaceutical itself and a three component release rate controlling matrix composition. Hallmark '717 teaches that the three components of the matrix composition are an alginate component, an enteric polymer component, and a pH independent gelling polymer. Hallmark '717 teaches that in the formulation the gelling polymer provides excellent binding and controlled release characteristics thereby facilitating the manufacturing processes. Hallmark ‘717 teaches that during dissolution, hydroxypropyl methylcellulose hydrates to form a gel layer to control drug release at low pH levels. Hallmark ‘717 further teaches at high pH levels enteric polymer increases erosion rate so as to maintain a constant dissolution rate regardless of tablet size. So reduction in tablet size does not reduce release rate (page 3, lines 4-14)

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Shell et al. and Hallmark '717 and have a dosage form characterized by a specific erosion rate to dissolution rate ratio in the formulation. One skilled in the art at the time the invention was made would have been motivated to use a specific erosion rate to dissolution rate ratio in the formulation because Hallmark '717 teaches that the various polymers provide specific characteristics in controlled release formulations. Hallmark '717 specifically teaches that at high pH levels, enteric polymers, such as methacrylic acid copolymers, increase erosion rate so as to maintain a constant dissolution rate regardless of tablet size. So reduction in tablet size does not reduce release rate. Methyacrylic acid copolymers are listed among the polymers that are taught by Shell et al. and the instant invention that are usable in the formulation. Therefore, the skilled artisan would have been motivated with a reasonable expectation of success in combining the references and using the polymers, specifically, methacrylic acid copolymers to control the release rates by using a polymer that will hold the dissolution rate constant as the erosion rate increases.

Each of the references is silent as to the specific ratio of approximately 1.1:1 to 5:1, where in the dissolution rate stays constant. However, the adjustment of particular conventional working conditions (e.g., erosion rate to dissolution rate ratios) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been

well within the purview of the skilled artisan and no more than an effort to optimize results.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

Claims 1-14, 18-20, and 27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Shell et al. (US 2001/0018070) in view of Louie-Helm et al. Publication (2001) and Cipro® Drug Information Sheet (2000).

Applicant's Invention

Applicant claims a method of delivering a pharmacologically active agent, ciprofloxacin, orally to a patient in a fed mode. Applicant claims the method comprising combining the ciprofloxacin with at least one biocompatible, hydrophilic polymer which upon imbibition of water swells unrestrained dimensionally to a size effective to promote gastric retention. Applicant further claims a method of treating a human patient suffering from a bacterial infection once daily with ciprofloxacin.

Determination of the scope of the content of the prior art (MPEP 2141.01)

The teachings of Shell et al. are incorporated herein by reference and are therefore applied in the instant rejection as discussed above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Shell et al. do not teach the specific active agent, ciprofloxacin, in the working examples or the method of treating a patient with a bacterial infection with ciprofloxacin as in claims 18-20. It is for this reason the Louie-Helm et al. Publication and the Cipro® Drug Information Sheet are joined.

Helm et al. teach that the pharmacokinetics of 2 formulations of gastric retentive tablets of ciprofloxacin hydrochloride and the immediate release tablet were compared in 15 healthy volunteers (Abstract). Louie-Helm et al. teach to achieve once daily administration; gastric retentive tables of ciprofloxacin hydrochloride were developed (page 1, col. 1-2, Introduction). Louie-Helm et al. teach the gastric retentive tablets are administered with food and swell to a size sufficient to be retained in the stomach in the fed mode. Louie–Helm et al. teach that to insure that ciprofloxacin would not be delivered to the colon, the period of 90% drug release in USP Type 1 dissolution testing was designed to be approximately 6 hours (page 1-2, col. 2, Experimental Methods)(claims 1-3, 11-14, and 19, delivery of ciprofloxacin, 2-12 hours, once daily, instant invention).

The Cipro ® (ciprofloxacin hydrochloride) Tablets and Cipro® (ciprofloxacin) Drug Information Sheets teach that Cipro® is a synthetic broad spectrum antimicrobial agent for oral administration (page 1, Description) (claims 11-14 and 18, ciprofloxacin, antimicrobial treatment, oral administration, instant invention). The Drug Information Sheet teaches on pages 5-6 that Cipro® is shown to be active against Pseudomonas,

Shigella, Salmonella, E. coli, Campylobacter, Enterobacter and *Bacillus anthracis* (claim 20, specific bacteria, instant invention).

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Shell et al., the Louie-Helm et al. Publication and the Cipro ® Drug Information Sheet and use ciprofloxacin as the active agent. Shell et al. teach that the invention provides enhanced absorption of soluble drugs that are absorbed mostly in the stomach or high in the gastrointestinal tract such as ciprofloxacin. One skilled in the art at the time the invention was made would have been motivated to use ciprofloxacin in the formulation because Shell et al. specifically teaches that ciprofloxacin is one of the preferred active agents. In addition, the Louie-Helm et al. Publication teaches it is within the purview of one skilled in the art to study the pharmacokinetics of a once daily gastric retentive ciprofloxacin hydrochloride tablet that was administered to patients and the Cipro ® Drug Information Sheet teaches the indications for the use of ciprofloxacin hydrochloride and ciprofloxacin.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

None of the claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616